

**UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**) MDL No. 2804
Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:)
Track Three Cases) Judge Dan A. Polster

**DEFENDANTS HBC SERVICE COMPANY AND GIANT EAGLE, INC.'S
TRIAL BRIEF**

Giant Eagle submits this Trial Brief to provide the Court with a brief statement of facts and to highlight some of the issues likely to arise during trial regarding witnesses and the presentation of evidence. Dkt. # 3758. Giant Eagle reserves the right to amend, supplement, or otherwise modify any of the positions set forth in this Brief, in advance of or during trial, including based on the evidence presented by Plaintiffs or any other Pharmacy Defendant.

Giant Eagle further notes that the parties' respective witness and exhibit lists are non-final and extremely lengthy. Accordingly, Giant Eagle reserves all rights to identify additional issues likely to arise at trial with respect to such witnesses and exhibits. Giant Eagle also maintains its objections to the Court's order limiting the Defendants' total trial time to 75 hours because that limitation effectively prohibits Giant Eagle from presenting a complete defense. Giant Eagle's submission of this Trial Brief is without waiver of those objections and is tailored to a presentation of the case aimed to meet the Court-imposed time limitations.¹

¹ Consistent with the Court’s guidance in Track One and Special Master Cohen’s instructions to the Pharmacy Defendants on August 6, 2021, Giant Eagle is omitting from this Trial Brief a discussion of the controlling law, as such laws have been discussed at length in the parties’ prior briefing and in Giant Eagle’s Brief in Support of Summary Judgment. To avoid any perceived waiver, and to ensure preservation of all legal arguments, Giant Eagle incorporates herein, to the extent necessary, all of the arguments previously raised by Giant Eagle and the other Pharmacy Defendants in this matter including, but not limited to, the elements of a public nuisance claim; applicability of the Ohio Product Liability Act to abrogate Plaintiffs’ claims; federal preemption of state law claims; failure to show unreasonable invasion of a public right by extensively regulated distribution of a lawful product; and failure to establish a violation of the Controlled Substances Act.

I. SUMMARY OF FACTS

Giant Eagle is a Pittsburgh-based, family-owned regional supermarket chain that features in-store pharmacies in some of its supermarkets. In total, Giant Eagle operates approximately 220 in-store pharmacies. At various points during the relevant time period, there were between 12 and 14 pharmacies in the two counties (two stores closed during the relevant time period).

Giant Eagle also operates its own distribution facility, which provides its grocery stores and pharmacies with a wide range of consumer products, as well as with over-the-counter and prescription medications. Prior to November 2009, Giant Eagle did not distribute any opioids. From November 2009 until September 2014, Giant Eagle operated a warehouse distribution center in Pennsylvania, HBC, that distributed only one product relevant to this litigation, and only to its own in-store pharmacies: generic hydrocodone combination products (“HCPs”). HBC stopped distributing Schedule III HCPs in early October 2014, one week before the DEA reclassified HCPs from Schedule III to Schedule II. In January 2016, Giant Eagle opened a new warehouse known as Giant Eagle Rx Distribution Center (“GERX”), which started distributing generic Schedule II-V controlled substances to Giant Eagle’s in-store pharmacies—and only Giant Eagle pharmacies—in March 2016.

Giant Eagle’s distribution facilities have an exemplary record of compliance with federal regulations. Between 2009 and 2020, the DEA, with the participation of at least twelve different DEA Diversion Investigators, conducted seven in-depth, on-site investigations of HBC and GERX, and each time the result was the same: the DEA determined that Giant Eagle’s distribution operations were in “**full compliance**” with all DEA-promulgated recordkeeping and security regulations in Title 21 of the Code of Federal Regulations, *including* the requirement to maintain

an effective SOM system to protect against diversion.² Given Giant Eagle’s unblemished record of “full compliance,” it is unsurprising that the DEA *never* issued an order to show cause, never issued any citations or letters of admonition, and never pursued any adverse actions against HBC or GERX.

Giant Eagle’s pharmacies have a similarly exemplary record of compliance with Ohio’s regulatory framework. As with its distribution centers, every Giant Eagle pharmacy in Lake County and Trumbull County was subject to frequent on-site inspections by the Ohio Board of Pharmacy, the agency responsible for ensuring that pharmacies dispense controlled substances in compliance with all applicable state and federal laws. Through 2019, the Ohio BOP conducted at least 92 inspections of the Giant Eagle pharmacies in the two counties. As part of these inspections, the Ohio BOP examined and evaluated the pharmacy’s dispensing systems and operations to ensure compliance with state and federal laws. With the exception of a few minor issues—which Giant Eagle quickly resolved—the Ohio BOP consistently concluded that Giant Eagle pharmacies were operating lawfully in compliance with all relevant laws and regulations. The Ohio BOP never identified Giant Eagle’s pharmacies in the two counties as possible diversion sites. The Ohio BOP agents who actually interacted with and inspected Giant Eagle pharmacies in Lake and Trumbull Counties (unlike the Plaintiffs’ hired litigation experts) confirmed that the pharmacies complied with Ohio and DEA security and dispensing regulations and operated lawfully at all times.

Giant Eagle never engaged in opioid diversion. In fact, the evidence will show that Giant Eagle acted lawfully at all times and never exhibited any of the hallmarks that the DEA and

² Prior to obtaining its Schedule III-V license in late 2009, Giant Eagle was also the subject of DEA investigations with respect to its List I chemical distribution in 2002, 2004, and 2008, none of which found any violations.

Plaintiffs' own experts have argued are indicative of a "bad distributor" or "bad pharmacy." The evidence will show, for example:

- Giant Eagle self-distributed at all times and never to third parties.
- Giant Eagle's opioid dispensing decreased in the two counties even while DEA quotas increased.
- Giant Eagle's dispensing ratio of controlled compared to non-controlled substances was far below (less than half) the DEA's threshold for suspicion requiring possible investigation.
- Compared to its in-county peers, Giant Eagle dispensed opioids at much lower MME levels per transaction, dosage unit, and day. For example, in terms of MMEs per transaction, no Giant Eagle pharmacy ranks in the *top 50* per transaction and Giant Eagle filled on average *less than one prescription per day* of high potency medications that are most likely to be abused.
- Cash payments for opioid prescriptions at Giant Eagle were consistent with cash payments for all drugs and well below the DEA's threshold for suspicion requiring possible investigation.

Giant Eagle did not just comply with all laws and regulations designed to prevent diversion—it *actively assisted* law enforcement in their efforts to prevent diversion, including by reporting illegal prescriptions and stopping diversion in its tracks. At the corporate level, Giant Eagle never advertised or promoted opioids, and it never implemented any other strategy or approach designed to increase opioid sales. Giant Eagle pharmacists employ extra internal controls not required by the DEA or Ohio BOP, including double-counting; back-counting (total number of pills left in inventory equals prior count minus current prescription being filled); perpetual inventory (inventory updated and checked after every transaction, rather than every 2 years as required by DEA regulations); monthly controlled substances inventory counts; and random inventory checks.

As a result of the above, Plaintiffs are unable to prove that Giant Eagle caused or contributed to a public nuisance. Giant Eagle and its pharmacists operated reasonably and lawfully

at all times, including by filling legitimate prescriptions issued by doctors and other trained medical professionals who had a duty to screen their patients for red flags of possible diversion prior to issuing the prescriptions. Plaintiffs have no proof that any such prescriptions were not legitimate and, to the contrary, the DEA agrees that nearly every prescription (up to 99.9%) issued by doctors and healthcare professionals are legitimate.

Plaintiffs also have no proof that any Giant Eagle pharmacists “knowingly” filled an illegitimate prescription which must be proven in order to find liability. Giant Eagle pharmacists generally have no authority to issue prescriptions or exercise medical judgment, and they are not responsible for setting, modifying, or overruling the prevailing standard of medical care which changes over time. As healthcare professionals, pharmacists have a duty to make sure patients have access to the medications their doctors prescribe for them and to fill doctors’ prescriptions unless there is a reason to believe they are not legitimate.

Plaintiffs’ “aggregate theory” fails to prove anything to the contrary and further fails to prove that any prescription filled by Giant Eagle was not legitimate, actually diverted, and/or caused any part of the alleged nuisance. Plaintiffs admit in their own complaints that the supply of opioids increased dramatically for a period of time due to the marketing practices of the manufacturers, which caused doctors to over-prescribe and the DEA to raise annual quotas, none of which is the responsibility of the Pharmacy Defendants. Finally, any current nuisance is the result of criminal behavior and illegal opioids such as heroin and fentanyl, and not prescription opioids.

II. WITNESSES

Giant Eagle has currently identified approximately fifteen (15) witnesses (six “most likely” and nine “likely”) plus fifty-four (54) joint witnesses (seventeen “most likely” and thirty-seven “likely”) to be called at trial. Giant Eagle anticipates presenting testimonial and documentary

evidence to show that it has always been in compliance with the security regulations of the Controlled Substances Act and, as such, is entitled to the “safe harbor” immunity from public nuisance that has been previously recognized by this Court. *See* Doc. # 3403 at 29-30; Doc. # 3177 at 45-47. *See also City of Cleveland v. Ameriquest Mortgage Securities, Inc.*, 621 F. Supp. 2d 513, 528 (N.D. Ohio 2009) (conduct that complies with regulations cannot be a nuisance); *Hager v. Waste Techs. Indus.*, 2002-Ohio-3466, 2002 Ohio App. LEXIS 3558 (Ohio Ct. App. 2002) (reaffirming “general rule” that “conduct which is fully authorized by statute or administrative regulation is not actionable as a public nuisance” and holding that “[s]ince [Defendant’s] waste incineration facility operates under sanction of law, based on that fact alone, it cannot be a common law public nuisance.”).

Giant Eagle will also present testimonial and documentary evidence of its security measures (including but not limited to its SOM system and cooperation with law enforcement), as well as Giant Eagle’s interactions with, and reliance upon, inspections by the DEA and Ohio BOP.

To the extent Giant Eagle determines it is necessary to do so at trial, Giant Eagle intends to call two expert witnesses:

1. Matthew Greimel, a retired DEA Special Agent and Field Office Acting Supervisor, will testify regarding the DEA’s enforcement of the security regulations; Giant Eagle’s integrated distribution operations, with controls at the warehouse, corporate, and pharmacy levels; the importance of DEA Diversion Investigators’ repeated inspections finding that Giant Eagle is in “full compliance” with the security regulations; and the flawed methodology of Plaintiffs’ expert James Rafalski.
2. Sandra K.B. Kinsey, R.ph, MBA, an expert with over 25 years’ experience in retail pharmacy operations, prescription filling, product sourcing, inventory management, supply chain, and regulatory compliance, will testify regarding (among other matters listed in her expert report) the opioid pharmaceutical market, the importance of the opioid medications at issue, Giant Eagle’s pharmacy operations, and Giant Eagle’s anti-diversion efforts, as well as provide testimony to rebut expert testimony likely to be proffered by Plaintiffs.

Giant Eagle also intends to present evidence through the testimony of two shared defense experts: (1) Kevin M. Murphy, Ph.D, on the issues identified in his expert report(s), including the economic and social factors that contributed to the misuse of, and increased mortality from, prescription and illicit opioids and the Plaintiffs' failure to prove causation; and (2) Robert E. Wailes, MD, on the issues identified in his expert report(s), including the current standards of care for opioid prescribing; the current standards of care for concurrent opioid, benzodiazepine, and/or muscle relaxer prescribing; how standards of care for opioid and concurrent controlled substances prescribing have changed during his 37-year career; the causes of illicit opioid-related deaths in the United States; the prescriber's perspective on the role of pharmacists in caring for patients who are prescribed opioids; the role of state medical boards in assessing whether prescribers adhere to medical standards of care; and the likelihood that Plaintiffs' "red flags" more frequently flag commonplace, legitimate prescribing as opposed to fraudulent or otherwise aberrant prescriber or patient conduct.

Giant Eagle may also present testimonial and documentary evidence regarding non-party contributors to the alleged public nuisance including, but not limited to, evidence regarding manufacturers and non-party distributors, as well as pill mill doctors and pharmacies, drug gangs, internet pharmacies, and medicine cabinet leakage. To the extent there is a finding of any liability and it becomes relevant in the first phase of this trial, Giant Eagle expects that issues will arise relating to the apportionment of fault as-between defendants and Giant Eagle reserves the right to present such evidence if necessary.

III. ANTICIPATED EVIDENTIARY ISSUES

Given the anticipated length and complexity of this case, as well as the anticipated number of witnesses and documents, Giant Eagle cannot identify with certainty or specificity all of the

evidentiary issues likely to arise at trial. Giant Eagle does anticipate, however, that several critical evidentiary issues will arise during trial, including but not limited to the following:

- Plaintiffs' improper reliance upon "aggregate proof" to meet the elements of but-for and proximate causation without any evidence of a single improperly distributed or dispensed controlled substance by Giant Eagle;
- Plaintiffs' likely invocation of several informal agency statements or publications that do not have the force of law, are accorded no weight in this lawsuit, and do not impose controlling legal requirements on anyone beyond the entity involved in the particular agency adjudication;
- Plaintiffs' improper attempts to shift the burden of proof onto the defendants—for example, by assuming that the lack of a document in a defendant's files setting out a decades-old policy means that such policy or practice either did not exist and/or was insufficient;
- Plaintiffs' improper attempts to conflate the actions of all defendants and/or to fail to properly delineate between the five (5) defendants at all times during Plaintiffs' presentation of evidence;
- Plaintiffs' improper reliance on events and/or conduct occurring outside the two counties (whether by Giant Eagle or others) that has no nexus to Lake and/or Summit County;
- Plaintiffs' improper attempts to distort Giant Eagle's lawful conduct and deem it unlawful, and/or to hold Giant Eagle liable for the potentially unlawful conduct of others;
- Any improper attempt by Plaintiffs to try to prove their case by introducing evidence relating to individual prescriptions despite routinely disclaiming the need to present such evidence;
- Plaintiffs' improper objections to defendants' presentation of evidence regarding non-party contributors to the alleged nuisance, including defendants in other tracks in this MDL and other persons/entities not named as parties in this MDL.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 19, 2021, the foregoing was served via e-mail to the following:

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